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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,046	05/28/2002	Adel Youakim	NEU-00118.P1	8000

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EXAMINER	
SAIDHA, TEKCHAND	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,046	YOUAKIM ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *2,8,15-18,21-24 and 26-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,9-14,19,20 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 May 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/22/03 & 9/29/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The petition filed September 19, 2005, to revive this application abandoned unintentionally under 37 CFR 1.137(b), having been reviewed by the Office of Petitions, is GRANTED. A copy of this decision was mailed to the Applicants in November 16, 2005.

Election

2. Applicant' s election without traverse of Group I (*all in-part*, claims 1, 3-7, 9-14, 19-20 & 25, drawn to nucleic acid molecules of SEQ ID NO: 1-10), in the reply filed on 9/19/2005, along with the request to revive this application is acknowledged.

3. **Claims withdrawn:**

Claims 1, 3-7, 9-14, 19-20 & 25, drawn to nucleic acid molecules of **non-elected** SEQ ID NO: 11-43) and claims 2, 8, 15-18, 21-24 & 26-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Claims 1, 3-7, 9-14, 19-20 & 25, drawn to nucleic acid molecules of SEQ ID NO: 1-10, vector, host cell and method of making the protein recombinantly are under consideration in this examination.

5. ***Priority***

Applicant' s claim for domestic priority under 35 U.S.C. 119(e), filed 01 June 1999, is acknowledged.

6. ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

7. ***Claim Objections***

Claims 1-2, 5-7, 9 & 19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 5-7, 9 & 19 depend upon non-elected claim 2.

Applicants' are required to amend the claim and/or place the claims in proper dependent form. Claims 1-2 recite non-elected SEQ ID Nos. Correction is required.

8. ***35 U.S.C. § 112, first paragraph (Written Description)***

Claims 1, 3-7, 9-14, 19-20 & 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 1, 3-7, 9-14, 19-20 & 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of nucleic acid molecules comprising the sequence(s) of SEQ ID Nos. 1-10 or a nucleic acid molecules comprising a polynucleotide which is at least 95% identical to each of the sequences of SEQ ID Nos. 1-10, or a nucleic acid molecule at least 10 bases in length that would hybridize to each of the nucleic acid sequences of SEQ ID Nos. 1-10, or wherein each of the isolated nucleic acid sequences of SEQ ID Nos. 1-10 encode a polypeptide epitope, or a fragment of their correspondingly

encoded polypeptide, or a species homologue; or wherein the isolated nucleic acid molecule of each of the sequences of SEQ ID Nos. 1-10 comprises sequential nucleotide deletion from either the C-terminus or N-terminus, the corresponding vector, host cell and method of making the protein recombinantly.

The specification does not contain any disclosure of the function(s) of any of the nucleic acid sequences that are 100% or 95% identical to SEQ ID Nos. 1-10 or fragments thereof. The genus of nucleic acids having 95% sequence homology is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated nucleic acids are encompassed within the scope of these claims, including partial nucleic acid sequences. The specification discloses the structure of several DNA sequences. However, there is no disclosed correlation between these structures to any specifically assigned or known function. The instant specification on page 24, lines 32-33, describe the uses of polynucleotides in the identification of chromosome. The encoded polypeptide(s) of the invention is said to be useful for the treatment of disease(s) (*see* page 29, lines 31-34), wherein the exemplified diseases are hypothetical, and do not quite relate to specific disease(s) and are specific to the encoded protein. On page 28 of the instant specification the polypeptide(s) is described as useful for assaying protein levels in biological sample using antibody based techniques such as enzyme linked immunosorbent assay (ELISA) & radioimmunoassay (RIA). These may be considered as generic functions for the protein, nucleic acid, and antibodies. However, there is no clear-cut description of the function of the polynucleotide or the encoded protein or polypeptide epitope or species homologue to have any specific biological activity or that the polynucleotide or the encoded protein to be associated with any specific disease or disorder. Therefore without a

specifically defined function for the claimed polynucleotides, the generic uses for the polynucleotides or proteins or antibodies do not fulfill the written description requirement. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Therefore, the written description requirement is not satisfied.

9. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 is directed to a genus of polynucleotide molecules representing polymorphic form(s) or species homologues encoded by the sequences of SEQ ID NO: 1-10 which encompass allelic variants or species homologues.

An allelic variant or species homolog sequence is an alternative form of the gene which may result in at least one mutation in the nucleic acid sequence. Alleles may result in altered mRNAs or polypeptides whose structure or function may or may not be altered. This definition does not provide any specific information about the structure of naturally occurring alleles or polymorphs or species homologues or variants of SEQ ID Nos. 1-10 (i.e. where is the likely regions within which mutations are likely to occur) nor discloses any function for naturally occurring polymorphs or species homologues. There is no description of the mutational sites that exist in nature, and there is no description of how the structures of SEQ ID Nos. 1-10 relate to the structures of any naturally occurring polymorphs or species homologues. The general knowledge in the art concerning alleles dose not provide any indication of how one polymorph is representative of unknown polymorphs. The nature of polymorphism is such that they are variant structures, and in the present state of the art structure of one does not provide guidance to the structure of others. Therefore, many functionally unrelated polypeptides are encompassed within the scope of these

claims. The specification discloses specific species of the claimed genus i.e., the sequences of SEQ ID Nos. 1-10, which are insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

10. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 25 is directed to a gene corresponding to the cDNA sequences of SEQ ID Nos. 1-10. The specification discloses that SEQ ID Nos. 1-10. No gene is described. Claim 25 is rejected under this section of 35 USC 112 because the claim is directed to genomic DNA sequences not disclosed in the specification. No description has been provided of the genomic DNA sequences encompassed by the claim. Applicants have not adequately described the nature of the genomic DNA or the corresponding cDNA sequence. No structural information, beyond the partial characterization of SEQ ID Nos. 1-10 has been provided by Applicants which would indicate that they had possession of the claimed gene.

Eukaryotic genes (genomic DNA sequences) are well known in the art of molecular biology to contain elements of structure not present in cDNA sequences. For example, introns are regions of DNA that interrupt coding sequences in eukaryotic genes. In different genes, introns have been detected that are as large as 2000 base pairs. Some genes have as many as 16 introns. Because cDNA libraries are generated by reverse transcription of mRNA which has been processed in the nucleus to remove introns, intron sequences are not

present in cDNA libraries. Since the claimed gene or genomic DNA has not been described and, a person skilled in the art would not recognize that Applicants had possession of the claimed invention at the time of filing.

11. Claims 1, 3-7, 9-14, 19-20 & 25 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

Applicants disclose nucleic acid sequences (SEQ ID Nos. 1-10) encoding amino acid sequences which remains undescribed but may be deduced by one skilled in the art. Based on reasonable sequence homology, perhaps, the polynucleotide of SEQ ID Nos. 1-10 are sought to be useful for chromosomal identification or the polypeptides encoded by the polynucleotide of SEQ ID Nos. 1-10 would be useful for assaying proteins in biological sample (page 28), or for treating disease(s) (page 29), or for testing one or more biological activities (page 30), which are generic utilities.

Applicants are uncertain about the use of the polynucleotide or polypeptide, which is substantiated by statements on page 30 (3rd paragraph) of the instant specification and reads as: " If these polynucleotides and polypeptides do exhibit activity in a particular assay, it is likely that these molecules may be involved in the diseases associated with the biological activity. Thus, the polynucleotides and polypeptides could be used to treat the associated disease."

The specification does not identify any specific function associated with the polynucleotide or the encoded polypeptide. No specific role of the protein or polynucleotide is shown to be associated to any disease or biological processes. It is nearly impossible from sequence homology alone to attribute a specific and substantial function for the polynucleotide (or the encoded protein), and none

have been asserted. Therefore without a specifically defined function for the claimed polynucleotides, the generic uses for the polynucleotides or proteins (or antibodies) do fulfill the utility requirement.

It appears that the main utility of the polypeptide and nucleic acid is to carry out further research to identify the biological function and possible diseases associated with said function. Substantial utility defines a real world use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a ' real world' context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-7, 9-14, 19-20 & 25 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

12. ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(1) Claims 4 & 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession numbers H94042 (1996) or T91795 (1995). Claims are drawn to nucleic acid molecules, at least 10 bases in length & hybridizable under stringent conditions to the nucleic acid of SEQ ID NO: 1, or encoding a fragment of any length or a polypeptide epitope of any length. Accession numbers H94042 or T91795 reads upon the claimed fragments and the references are therefore anticipatory. *See* the enclosed sequence search alignment between SEQ ID NO; 1 and H94042 or T91795 disclosing 10 or more contiguous matches. Claim 4, recite 10 bases, which do not have to be contiguous matches.

(2) Claims 4 & 6-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Accession number AQ167893 (Oct' 1998). Claims are drawn to nucleic acid molecules, at least 10 bases in length hybridizable under stringent conditions to the nucleic acid of SEQ ID NO: 2, or encoding a fragment of any length or a polypeptide epitope of any length. Accession number AQ167893 reads upon the claimed fragments and the reference is therefore anticipatory. *See* the enclosed sequence search alignment between SEQ ID NO; 2 and AQ167893.

(3). Claims 3-4 & 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number HSU77643 (Mar' 1998). Claims are drawn to nucleic acid molecules, at least 10 bases in length hybridizable under stringent conditions to the nucleic acid of SEQ ID NO: 3, or encoding a fragment of any length or a polypeptide epitope of any length, or that the nucleic acid is at least 95% homologous to SEQ ID NO: 3. Accession number HSU77643 reads upon the claimed fragments or homology. The reference is therefore anticipatory. *See* the enclosed sequence search alignment between SEQ ID NO: 3 and HSU77643. (76 matches out of 79 is about 96% similarity).

(4). Claims 4 & 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number HSU77643 (Mar' 1998). Claims are drawn to nucleic acid molecules, at least 10 bases in length hybridizable under stringent conditions to the nucleic acid of SEQ ID NO: 4, or encoding a fragment of any length or a polypeptide epitope of any length. Accession number HSU77643 reads upon the claimed fragments and the reference is therefore anticipatory. *See* the enclosed sequence search alignment between SEQ ID NO: 4 and HSU77643.

(5). Claims 4 & 6-7 are rejected under 35 U.S.C. 102(e) as being anticipated by SEQ ID NO: 25 in USP 6,709,855. Claims are drawn to nucleic acid molecules, at least 10 bases in length hybridizable under stringent conditions to the nucleic acid of SEQ ID NO: 5, or encoding a fragment of any length or a polypeptide epitope of any length. SEQ ID NO: 25 in USP 6,709,855 reads upon the claimed fragments and the reference is therefore anticipatory. *See* the enclosed sequence search alignment between SEQ ID NO: 5 and SEQ ID NO: 25 in USP 6,709,855.

(6). Claims 3-4 & 6-7 are rejected under 35 U.S.C. 102(e) as being anticipated by SEQ ID NO: 283 in USP 6,225,054. Claims are drawn to nucleic

acid molecules, at least 10 bases in length hybridizable under stringent conditions to the nucleic acid of SEQ ID NO: 6, or encoding a fragment of any length or a polypeptide epitope of any length, or that the nucleic acid is at least 95% homologous to SEQ ID NO: 6. SEQ ID NO: 283 in USP 6,225,054 reads upon the claimed fragments or homology. The reference is therefore anticipatory. *See* the enclosed sequence search alignment between SEQ ID NO: 6 and SEQ ID NO: 283 in USP 6,225,054. (306 matches out of 323 is about 96% similarity).

(7). Claims 4 & 6-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Accession No. AAV71777 in USP 5,846,777. Claims are drawn to nucleic acid molecules, at least 10 bases in length hybridizable under stringent conditions to the nucleic acid of SEQ ID NO: 7, or encoding a fragment of any length or a polypeptide epitope of any length. Accession No. AAV71777 in USP 5,846,777 reads upon the claimed fragments and the reference is therefore anticipatory. *See* the enclosed sequence search alignment between SEQ ID NO: 7 and Accession No. AAV71777 in USP 5,846,777 (91.6% sequence similarity).

(8). Claims 3-4, 6-7 & 9 are rejected under 35 U.S.C. 102(e) as being anticipated by SEQ ID NO: 107 in USP 6,475,753. Claims are drawn to nucleic acid molecules, at least 10 bases in length hybridizable under stringent conditions to the nucleic acid of SEQ ID NO: 8, or encoding a fragment of any length or a polypeptide epitope of any length, or that the nucleic acid is at least 95% homologous to SEQ ID NO: 8. SEQ ID NO: 107 in USP 6,475,753 reads upon the claimed fragments, or homologue, or homology. The reference is therefore anticipatory. *See* the enclosed sequence search alignment between SEQ ID NO: 8 and SEQ ID NO: 107 in USP 6,475,753. (102 matches out of 103 is about 98% similarity).

(9). Claims 3-4, 6-7 & 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number AA133211 (May 1997). Claims are drawn to nucleic acid molecules, at least 10 bases in length hybridizable under stringent conditions to the nucleic acid of SEQ ID NO: 9, or encoding a fragment of any length or a polypeptide epitope of any length, or that the nucleic acid is at least 95% homologous to SEQ ID NO: 9. Accession number AA133211 reads upon the claimed fragments or homology or homologue. The reference is therefore anticipatory. *See* the enclosed sequence search alignment between SEQ ID NO: 9 and AA133211. (29 matches out of 30 is about 97% similarity).

(10). Claims 3-4, 6-7 & 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession No. HUMLMP7A (Aug' 1993). Claims are drawn to nucleic acid molecules, at least 10 bases in length hybridizable under stringent conditions to the nucleic acid of SEQ ID NO: 10, or encoding a fragment of any length or a polypeptide epitope of any length, or that is at least 95% homologous to SEQ ID NO: 10. Accession No. HUMLMP7A reads upon the claimed fragments or homology or homologue. The reference is therefore anticipatory. *See* the enclosed sequence search alignment between SEQ ID NO: 10 and Accession No. HUMLMP7A. (84 matches out of 85 is about 98% similarity).

13. The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 in view of the AIPA and H.R. 2215 that forms the basis for the rejections under this section made in the attached Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

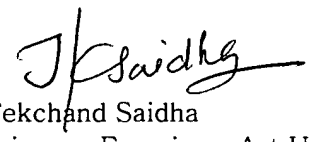
Claims 3-4, 6-7 & 9 are rejected under 35 U.S.C. 102(e) as being anticipated by SEQ ID NO: 79 in USP US20030064072A1 (March 12, 1999). Claims are drawn to nucleic acid molecules, at least 10 bases in length hybridizable under stringent conditions to the nucleic acid of SEQ ID NO: 10, or encoding a fragment of any length or a polypeptide epitope of any length, or that is at least 95% homologous to SEQ ID NO: 10. SEQ ID NO: 79 in USP US20030064072A1 reads upon the claimed fragments or homology or homologue. The reference is therefore anticipatory. *See* the enclosed sequence search alignment between SEQ ID NO: 10 and SEQ ID NO: 79 in USP US20030064072A1. (84 matches out of 85 is about 98% similarity).

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner' s supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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